CARPMAELS & RANSFORD

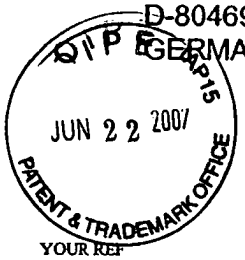
CHARTERED PATENT ATTORNEYS EUROPEAN PATENT ATTORNEYS TRADE MARK ATTORNEYS

TELEPHONE 020-7242 8692
FACSIMILE 020-7405 4166
WEBSITE www.carpmaels.com
E-MAIL email@carpmaels.com

43-45 BLOOMSBURY SQUARE
LONDON WC1A 2RA

AND AT MUNICH

European Patent Office
Erhardtstrasse 27
D-80469 Munich
GERMANY



YOUR REF

OUR REF O004005EP:AJF/swi

BY FAX

17th January 2007

COPY

Dear Sirs,

Re: European Patent No. 1317227 (Application No. 01968890.2)
"Implantable prosthesis" C. R.Bard, Inc.

I refer to your communication of 11th July 2006, and to the Proprietor's letter of 31st October 2006.

The Opponent considers that the claims of the Auxiliary Request do not meet the requirements of Articles 84, 123(2), 54 and 56 EPC. Accordingly, having regard to the second paragraph of the Proprietor's letter of 31st October 2006, it is assumed that the Main Request is maintained.

The Opponent maintains its request for oral proceedings. For the avoidance of doubt, I propose to address the Opposition Division in English. I imagine that the Proprietor's representative will do the same.

The Opponent also maintains its request for the patent to be revoked in its entirety, for the following reasons.

FACSIMILE MESSAGE

To: **EPO Munich**
Fax No.: **00 49 89 2399 4465**

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Main Request

Novelty

D5

The objection of lack of novelty in view of D5 is maintained. Contrary to the assertion of the Proprietor, the Opponent has not acknowledged that the product disclosed in D5 is not an implantable prosthesis. On the contrary, I stated in my letter of 16th August 2005 that the product disclosed in D5 is not described as an implantable prosthesis. There are no structural features of the product disclosed in D5 which preclude its use as an implantable prosthesis. It therefore constitutes an implantable prosthesis within the meaning of claim 1 of the Main Request, whether or not it is so described in D5.

In relation to the requirement in claim 1 for "a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs", the Proprietor points to column 2, line 46 of D5, and the reference therein to "non-adherent characteristics". In so doing, however, the Proprietor misrepresents the disclosures of D5.

The dressing disclosed in column 2 of D5 is a laminate of a cellulosic material and a polypropylene layer. The cellulosic layer is first attached to a polypropylene fibre layer by needling (column 2, lines 30-42). The laminate is then fed through heat rolls to fuse the resin (i.e. the polypropylene) and thereby to provide a smooth surface with non-adherent characteristics.

The non-adherent polypropylene layer of the product described in D5 thus corresponds to the "barrier layer" of claim 1. The cellulosic layer, which remains distinct from the non-adherent propylene layer (see, for example, Figure 2 of D5) is certainly a "fabric that is susceptible to the formation of adhesions with tissue and organs".

In relation to the requirement in claim 1 that the peripheral barrier "inhibits the formation of adhesions with tissue and organs", the Proprietor asserts that it cannot be assumed that the crown or frame (12) surrounding the laminated pad in D5 would fulfil this function. However, D5 discloses that the frame may be fabricated from polypropylene (column 3, lines 2-3). Polypropylene is also used as a barrier material in the opposed patent (see, for example, column 8, lines 25-28).

The product described in D5 therefore has all of the prescribed characteristics of the prosthesis of claim 1 of the Main Request, which accordingly lacks novelty.

At least claims 2, 5-7, 14 and 29 of the Main Request also lack novelty in view of D5.

WO00/16822 (hereafter D6)

At least claims 1, 2, 8, 9, 14, 29 and 30 of the Main Request also lack novelty in view of WO00/16822 (D6), a copy of which is enclosed.

D6 relates to compositions and methods for tissue repair. On page 16, lines 5-23, there is described the preparation of an implantable prosthesis comprising a polypropylene mesh which is completely surrounded by a collagen matrix.

The polypropylene mesh is clearly a repair fabric that is susceptible to the formation of adhesions with tissue and organs (see, for example, page 2, lines 2-3).

Moreover, the collagen matrix is effective to inhibit the formation of adhesions (page 18, lines 22-26).

Since the polypropylene mesh is completely surrounded by the collagen matrix, it also constitutes a peripheral barrier extending about at least a portion of the outer peripheral edge of the layer of polypropylene mesh, to inhibit the formation of adhesions between the portion of the outer peripheral edge of the polypropylene mesh and adjacent tissue and organs.

The product described in D6 therefore also has all of the prescribed characteristics of the prosthesis of claim 1 of the opposed patent.

Inventive step

An objection of lack of inventive step was raised in my letter of 16th August 2005 based on D1 and the prior availability of Parietex® Composite. That objection is maintained, and further elaborated below.

It was well known at the priority date of the opposed patent that the edge of a fabric implant represents a potential site for adhesions, and that it should therefore be prevented from coming into contact with internal organs. As evidence in support of this assertion, the Opponent relies on:

D1

Matapurkar *et al.*, World J. Surg. 15, 768-770, 1991 (hereafter D7, copy enclosed)

Baptista *et al.*, J. Am. Coll. Surg., March 2000 (hereafter D8, copy enclosed[1])

As noted in my letter of 16th August 2005, the projecting portion of the absorbable film disclosed in D1 is said to "protect the prosthesis from visceral contacts" (page 8, lines 7-12). This manifestly does not mean that the upper surface of the fabric (as seen in Figure 1 of D1) is protected from contact with visceral tissue, because the whole point of the prosthesis disclosed in D1 is that the upper surface of the fabric allows ingrowth of tissue. Equally clearly, the projecting portion of the absorbable film cannot be intended to protect the opposite face of the fabric from visceral contacts, because that face of the fabric is already protected by the film. Plainly, therefore, the projecting portion of the absorbable film is intended to protect the edge of the fabric from visceral contacts.

D7 is a report of a new procedure for hernia repair using a polypropylene mesh. In this technique, the polypropylene mesh is sandwiched between two layers of peritoneum of the hernia sac, as illustrated in Figures 1 to 3. As noted on page 770, left-hand column, lines 8-11:

[1] The enclosed copy is taken from the website of the American College of Surgeons. A copy as published in the Journal of the American College of Surgeons will follow shortly.

> "The mesh does not come in direct contact with either the abdominal viscera or tissues of the anterior abdominal wall. This provides safety to the mesh as well as abdominal viscera."

It is particularly important to note the technique by which all contact between the mesh and the abdominal viscera is prevented. The left-hand edge of the mesh (as seen in Figures 1 to 3) is folded back behind a portion of the peritoneum (Figure 3). In this way, not only the major surface but also the edge of the mesh is protected from visceral contact.

D8 is a report of an investigation into formation of abdominal adhesions to polypropylene mesh implants. Under the heading of "technical considerations", the authors report that:

> "Pilot studies demonstrated that interrupted sutures encouraged omentum or intestine to adhere to the cut edge of the prosthetic material, occasionally even to permit visceral herniation between sutures into the subcutaneous space. We subsequently used continuous monofilament polypropylene suture, everting the edge of the prosthesis and the cut edge of the abdominal wall away from the abdominal cavity." [emphasis added]

Accordingly, the problem of covering the edge of a mesh implant to prevent visceral contact was recognised in the art. The various embodiments disclosed in the opposed patent are merely obvious ways of solving this known problem.

Starting, for example, with the mesh implant disclosed in US-A-5593441 (hereafter D9, copy enclosed), one obvious way of covering the edge of the mesh was to provide a frame or border of the kind disclosed in D5 or US-A-5695525 (hereafter D10, copy also enclosed).

Starting, as an alternative, with the mesh implant disclosed in D1, one obvious way of covering the edge of the mesh was to fold the projecting portion of the film (3) over the edge, and to secure it by any suitable means. This method was particularly obvious in view of D7 and D8, both of which teach everting the edge of a mesh implant.

Auxiliary Request

As a preliminary matter, it is not clear from the Proprietor's submissions of 21st April and 31st October 2006 whether the Auxiliary Request consists of a single claim, or whether it also includes claims 2 to 31 of the Main Request.

Clarity

Claim 1 of the Auxiliary Request does not meet the requirements of Article 84 EPC. In particular, it is not clear what is meant by the peripheral barrier extending "between the first and second surfaces" of the repair fabric. For example, it could mean that the peripheral barrier extends through the thickness of the fabric. Such a construction could be achieved by impregnating the fabric with a barrier material, as disclosed in D6.

Alternatively, it could mean that the peripheral barrier is in contact with both surfaces of the fabric, as in Figure 6 of the opposed patent.

Added matter

Claim 1 of the Auxiliary Request does not meet the requirements of Article 123(2) EPC. The only embodiment in the originally-filed application which could reasonably be described as having a peripheral barrier which "extends between" the first and second surfaces of the repair fabric is that of Figure 6. In this embodiment, however, the peripheral barrier is formed from the barrier layer. There is no disclosure in the original application of a peripheral barrier which "extends between" the first and second surfaces of the repair fabric, wherein the peripheral barrier is not formed from the barrier layer.

Novelty

Claim 1 of the Auxiliary Request lacks novelty in view of D6. As discussed above in relation to the Main Request, the product disclosed in D6 comprises a polypropylene mesh which is completely surrounded by a collagen matrix. The collagen matrix therefore "extends between" the major surfaces of the polypropylene mesh, on either of the two interpretations of "extends between" discussed above.

Claim 1 of the Auxiliary Request also lacks novelty in view of D5. Figure 6 of the opposed patent makes clear that the peripheral barrier may be formed from part of the barrier layer. Accordingly, there appears to be no reason why the peripheral barrier can not alternatively be formed in part from the barrier layer and in part from a separate element as shown in Figure 3 of D5.

Inventive step

The subject-matter of claim 1 of the Auxiliary Request does not involve an inventive step in view of a combination of D9 with D5 or D10, or in view of a combination of D1 with D7 or D8, for the reasons discussed above in relation to the Main Request

Yours faithfully,

Adrian Fisher

FISHER, ADRIAN JOHN

Enc. WO 00/16822 (D6)
Matapurkar *et al.* (D7)
Baptista *et al.* (D8)
US-A-5593441 (D9)
US-A-5695525 (D10)

cc Mr Ian Grey, Venner Shipley (ref /49262GEN1)